

GUIDANCE

THE MATERIALS AND ARTICLES IN CONTACT WITH FOOD (SCOTLAND) REGULATIONS 2007

WARNING: this guidance has been prepared to provide information about the Regulations; it should not be taken as an interpretation of the law. It is not a substitute for the Regulations nor should it be read in isolation from, but in conjunction with, them.

Who should read this note.

This guidance is aimed at all companies that manufacture, process, distribute, use or sell materials and articles that are intended for use in contact with food. It is also aimed at enforcement authorities, as ultimately, they are responsible for enforcing the legislation. It may also be of interest to others with an interest in the legislation. These guidance notes provide a short summary of the new Regulations in so far as they relate to Scotland only. The other administrations in England, Wales and Northern Ireland will make separate parallel legislation.

Why you should read this note - compliance.

Within the European Union it is the responsibility of the manufacturer, importer or distributor of food contact materials and articles, or those who place them in contact with food prior to sale, to ensure that their products comply with the appropriate legislation. Unlike the system administered by the Food and Drug Administration (FDA) in the United States of America that many businesses will be familiar with, there is no harmonised system of prior approval or authorisation of food contact materials within the EU. It is possible that, in the event of prosecution for an alleged offence under these Regulations, defendants might avail themselves of the defence of due diligence provided for in the Food Safety Act 1990, as amended. In order to succeed such a defence would most likely require evidence that the defendant had taken all reasonable precautions to avoid committing the alleged offence, including, probably, documentary evidence that the material or article complied with the law.

The European Legislation

The European Commission and the Member States of the European Union are working towards a fully harmonised set of rules that will apply to food contact materials and articles across the EU. The aim is to protect consumers from harmful effects of eating food contaminated by chemicals that might have migrated from materials and articles with which the food had been in contact. This

harmonisation will provide businesses with one set of rules to comply with throughout the EU instead of a plethora of national rules in different EU Member States.

A new piece of European legislation entitled 'Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food' (the "GMP Regulation"), entered into force on 18th January 2007. This Regulation will apply from 1 August 2008 and is directly applicable in all EU Member States

The Materials and Articles in Contact with Food (Scotland) Regulations 2007 also implements Commission Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs, however this guidance relates solely to the GMP aspects of the new regulations.

Detail

Under Article 3 of the Framework Regulation, (EC) No. 1935/2004, there is a general requirement that all materials and articles falling within the scope of that Regulation have to be manufactured in compliance with 'good manufacturing practice (GMP)'. However, the term has not been further elaborated until now. The new GMP Regulation now does this and establishes the principles to be observed, proportionately, by businesses. It also lays down some specific requirements that apply to processes involving the application of printing inks to the non-food contact side of a material or article.

The GMP Regulation applies to those materials and articles within the scope of Regulation 1935/2004 and lays down detailed principles to be incorporated into GMP protocols to ensure uniformity and conformity amongst Member States across the EU. The GMP Regulation seeks to ensure that materials and articles intended for use in contact with food are consistently produced and controlled to conform with the rules applicable to them and with quality standards appropriate to their intended use. This will require that businesses look at the intended use of their products to ensure that different uses do not lead to unexpected demands on the performance of the material used in their manufacture. This will prevent higher than intended migration arising from say, use in hot conditions during heating food than when use has only been anticipated in cool conditions such as in a refrigerator. Different food types may also cause different migration behaviour from different food contact materials and manufacturers have to ensure their products can cope with foreseeable food contact.

The GMP Regulation will apply from 1 August 2008 and is directly applicable in all EU Member States. The time between entry into force of the Regulation and the application of its provisions provides time for those businesses that are affected by the Regulation to ensure they have sufficient provisions in place to meet its requirements on quality control systems, procedures and documentation.

The GMP Regulation will apply to all sectors and to all stages of manufacture, processing and distribution of these food contact materials and articles, but will exclude the production of starting

substances used in their manufacture. The detailed rules set out in the Annex to the GMP Regulation apply to the relevant individually mentioned materials and processes, as appropriate. Currently only requirements specific to printing inks are given.

Implementing provisions for the Enforcement of the GMP Regulation

The Materials and Articles in Contact with Food (Scotland) Regulations 2007 will provide for the enforcement of the GMP Regulation in Scotland by the enforcement authorities as defined by the Food Safety Act 1990 as amended, and is the same as the enforcement of other elements of the food law as it applies in Scotland. They will also put in place offences that may be prosecuted before the Courts where alleged breaches of the GMP Regulation arise, defences against alleged breaches under particular circumstances, and penalties that may be applied by Courts upon conviction. The Good Manufacturing Practices part of the regulations will come into force on 1 August 2008.

Penalties for infringement of the GMP Regulation.

The 2007 Regulations also contain levels of penalty that will apply in cases of infringement of the GMP Regulation. These penalties are in line with those of the Food Safety Act 1990 that apply elsewhere in our food law, as follows: Any person who fails to comply with the requirements of Article 4 of the GMP Regulation is guilty of an offence under these and other regulations dealing with materials and articles in contact with food. Any such person is liable on conviction on indictment to a fine or imprisonment for a term not exceeding two years or both; on summary conviction to a term of imprisonment not exceeding 6 months or a fine or a fine not exceeding level 5 on the standard scale or both.

Enforcement

Enforcement of the GMP Regulations is primarily the responsibility of local authorities. This is shared between central government and local government. While the making of legislation in the UK is the function of central government, the enforcement of food law is primarily (but not solely) the responsibility of the 499 local authorities in the UK, and more specifically Environmental Health Officers (EHOs) and Trading Standards Officers (TSOs).

Purpose of the Scotland Regulations - summary

The Materials and Articles in Contact with Food (Scotland) Regulations 2007 will:

- provide for the enforcement in Scotland of Regulation (EC) No. 2023/2006 by the enforcement authorities and for certain necessary provisions consequent upon action that may be taken by them;
- revoke *The Materials and Articles in Contact with Food (Scotland) Regulations 2005* and re-enact their provisions, taking into account the enforcement provisions of the GMP Regulation.

- put in place offences that may be prosecuted before the Courts where alleged breaches of the GMP Regulation arise;
- provide for defences against those alleged breaches under particular circumstances, and for penalties to apply on conviction of an offence under the Regulations;
- make any person who fails to comply with the requirements of Article 4 of the GMP Regulation is guilty of an offence under these and other regulations dealing with materials and articles in contact with food. Any such person is liable on conviction on indictment to a fine or imprisonment for a term not exceeding two years or both; and on summary conviction to a term of imprisonment not exceeding 6 months or a fine not exceeding level 5 on the standard scale or both and

This guidance relates solely to GMP, and not to Commission Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs which is also implemented by these regulations.

Further Information

If you have any questions about these or any other regulations governing food contact materials and articles, please contact:

Fiona Bruce
Food Standards Agency Scotland
Contaminants, Hygiene, Additives & Shellfish Branch
6th Floor, St Magnus House, 25 Guild Street, Aberdeen AB11 6NJ
Tel No 01224 285170
Fax No 01224 285168
E-mail: fiona.bruce@foodstandards.gsi.gov.uk

Other information about food contact materials is available from the Agency's website at: www.food.gov.uk/industry/foodcontactmaterials

The information that is available includes explanatory notes on all food contact materials legislation, including European Council Resolutions and policy statements, European Regulations and Commission Directives, United Kingdom research and development, and chemical surveillance. The results of completed surveillance can be viewed from this point and although work predating the formation of the Agency can be accessed from the site archive. You can also access information the Working Party on Chemical Contaminants from Food Contact Materials in determining and reviewing work on research and development in this area.

Fiona Bruce

Contaminants, Hygiene, Shellfish and Additives Branch

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